REMARKS

Reconsideration of this application is requested.

Claims 9 and 10 have been amended to obviate the Examiner's Section 112, 2nd ¶ rejection. The deleted reference to "analyte analogue" is redundant in the context of the applicants' claims as the analogue also qualifies as the analyte. The amendment of claims 9 and 10, therefore, does not affect the claim scope.

The claim changes are shown in the Appendix hereto.

The Examiner is requested to reconsider the Section 112, 2nd ¶ rejection of claims 2-10 in view of the amendments to claims 9 and 10.

The Examiner is also requested to reconsider and withdraw the Section 102(b) rejection of claims 9 and 10 as anticipated by May et al. The reference does not disclose the applicants' invention as defined by claims 9 and 10.

In rejecting claims 9 and 10 under Section 102(b), the Examiner has stated "May et al (U.S. Patent 5,622,871) disclose an assay device wherein a particulate direct label is sensitized with a specific binding agent and a non-specific protein to form a complex which can be detected". With respect, however, it is submitted that there is no such disclosure in May et al. It is true that May et al disclose an assay device wherein "a sample liquid reconstitutes a labelled reagent and carries it into a detection zone and a control zone, binding of said labelled reagent in these zones revealing the assay result", as required by applicants' claim 9. However, the fundamental feature of the present invention is that the labelled reagent is co-sensitized with both (1) a specific binding agent having specificity for the analyte of interest and (2) a non-specific protein which can participate in a control reaction. Nowhere is there any disclosure in May et al of an assay device comprising a co-

sensitized particulate labelled reagent as required by claim 9 of the present application. While it is true that May et al disclose an assay device which comprises a control zone, there is no disclosure that the control zone should include a reagent which is specific for a non-specific protein co-sensitized on the labelled reagent. Thus, for example, at Col. 5, May et al suggest that the "control zone can be loaded with an antibody that will bind to the labelled antibody from the first zone".

Accordingly, the applicants submit that the Examiner's Section 102(b) rejection should be withdrawn.

It is also respectfully submitted that claims 2-11 define subject matter which is not obvious from May et al in view of Sawai et al. Accordingly, reconsideration of the Section 103(a) rejection is requested.

Briefly stated, there is no valid basis for combining the references as the Examiner has done. However, even if combined, the references do not provide the applicants' invention of claims 2-11.

More specifically, it is noted that Sawai et al are equally silent with May et al as to the provision of a particulate label which is co-sensitized. Thus, the combination of May et al with the Examiner's secondary citation still does not disclose all the features of applicants' main claim 9.

Furthermore, as noted above, the combination of the two references is not one which a person skilled in the art would be at all likely to make. May et al relate to assay devices primarily using direct (i.e. visible) labels, the device being intended for use with liquid samples which are absorbed into a solid phase. In contrast, Sawai et al do not use assay devices. Instead, the method disclosed by Sawai et al is simply performed in the liquid phase in a reaction vessel. The result of the assay is

read by measurement of absorbance. The particles employed by Sawai et al are sensitized but otherwise unlabelled. The devices disclosed by May et al, and the method of Sawai et al, are so disparate that it is extremely difficult to see how the person skilled in the art could be led to combine the teachings of the two citations. Moreover, as pointed out above, even if the combination were made, it still does not teach all the essential features of the present invention.

For the reasons noted, withdrawal of the rejections of record and allowance of the application are requested.

Respectfully submitted,

PILLSBURY WINTHROP LLP

By _____
Paul N. Kokulis
Reg. No. 16773

PNK:mh
1600 Tysons Boulevard
McLean, Virginia 22102
Phone: (703) 905-2118

APPENDIX

Version with Markings to Show Changes Made

IN THE CLAIMS

The claims have been amended as follows:

9. (Twice Amended) An assay device of the type wherein a sample liquid reconstitutes a labelled reagent and carries it into a detection zone and a control zone, binding of said labelled reagent in these zones revealing the assay result, wherein said labelled reagent comprises a particulate direct label co-sensitized with

(iii) a specific binding agent having specificity for an analyte **[**or analyte analogue**]**, and

(iv) a non-specific protein which can participate in a control reaction with another specific binding agent which does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte **[**or analyte analogue**]** is accomplished in said detection zone.

10. (Twice Amended) An assay device according to claim 9, wherein said detection zone contains an immobilised specific binding agent which acts as a direct or indirect capture means for said analyte **[**or analyte analogue**]** but which does not bind to said non-specific protein, and said control zone contains a specific binding agent which binds said non-specific protein but does not bind said specific binding agent co-sensitised on said particulate direct label.